

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 10/051,459 Confirmation No. : 6980
Applicant : Hans BEER, et al.
Filed : January 22, 2002
TC/A.U. : 1743
Examiner : L ALEXANDER
Docket No. : 010743.50685US (formerly 2265.50685)
Customer No. : 23911
Title : SURFACE-ENHANCED MEMBRANE AND PROCESS
AND APPARATUS FOR PRODUCING SAME

DECLARATION UNDER 37 CFR §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Dr. Hans Beer, declare that:

1. I am a resident and citizen of Germany. I am the inventor of the invention described in the above-referenced application.

2. I have a doctor's degree of natural science and 34 years experience in the field of membrane technology. My current job title at Sartorius AG is Senior Scientist in the research & development department of membrane technology.

3. The present invention relates to an improved process for refining the surface of a membrane, and a resulting membrane used to identify specific analytes present in fluid media. In particular, the invention involves removal of impurities (also referred to as "dust") *after* the membrane is formed, but *before* the newly-formed membrane dries, by contacting the still-wet membrane with a cleaning agent and/or a cleaning device.

4. In the prior art, dust particles formed on membrane structures were minimized, but not eliminated, by measures such as filtration and/or precipitation of impurities from the feedstock liquids prior to the use of the feedstocks in a membrane formation process. These purification processes have proven to be less than completely successful, as the resulting membranes frequently still exhibited dust contamination, with the impurities interfering with the membranes' ability to provide crisp, well-defined target analyte indications. Moreover, the precipitation/purification processes add significant additional expense to the membrane production process.

5. The Beer, *et al.*, reference (U.S. Patent No. 5,628,960) cited in the U.S. Office Action of November 11, 2005 is an example of this prior art. In Beers, the cellulose derivatives to be used with the polymeric blend solution are re-precipitated prior to the addition of the polymeric blend solution and prior to the formation of a membrane. Beer does not suggest to one of skill in the art to remove impurities *after* formation of the membrane in the manner of the present invention, but before all the solvent has been evaporated.

6. In the U.S. Office Action of November 11, 2005, the Examiner states that the removal of contaminants prior to drying a feedstock would have had the same expected result (as Beer) in removing a contaminant, and thus the order of contaminant removal steps is a "result effective variable" and it would have been within the skill in the art to modify Beer to remove dust from a partially dried membrane "as optimization of a result effective variable."

7. Based on my knowledge and years of experience in this field, I can state this new process and resulting product are not mere "optimization" of a variable, but a completely new approach to membrane production that was not obvious to those of skill in the art.

8. With regard to the order of the process steps, it is not correct that removing contaminants prior to drying vs. after drying results in the same product.

9. First, one of skill in the art would know that the nature and order of steps in the prior art has been dictated by the product obtainable by the prior art technology, not as a result of mere choice of the order of interchangeable process steps. One of the primary reasons for using a feedstock purification process is that it is not possible to completely remove filter dust from a fully dried membrane using a conventional process such as brushing. In effect, the deficiencies of the post-membrane formation cleaning technologies force manufacturers to make their feedstocks as pure as reasonably possible to minimize the dust load on the finished membrane. One of skill would know that while attempts have been made to remove dust after membrane formation by physical action (*e.g.*, brushing), complete removal of dust has been difficult to achieve, and physical processes applied to dry membranes result in very undesirable damage to the membrane surface, in particular leaving irregular grooves in the membrane surface. These grooves degrade the membranes' ability to provide definitive analyte results, as the non-uniform or homogeneous surface

results in a turbulent front of a migrating analyte fluid, and asymmetry in migration which and render the sample results indistinct. Thus, the prior art steps were dictated by the need to minimize dust formation on the final dried product (and even then, the best the prior art could achieve with its processes was a contaminated membrane, unlike the essentially dust-free membrane obtained with the present invention).

10. Next, having worked in this field for many years, I am aware that the common expectation of those skilled in the art (even those with knowledge of the Beer and Johnson, *et al.* (U.S. Patent No. 4,894,157) references) would be that there is no way dust could be removed from a *partially-dried*, crude membrane *without destroying the membrane*. Thus, the development of the present inventive process and a resulting dust-free membrane by removing dust before the solvent is evaporated was a radical shift away from the common expectation in the art, and not a mere re-ordering of interchangeable process steps.

11. My view of the knowledge in the art is consistent with the fact that no one had previously pursued the present invention's approach. The significant additional expense associated with prior art feedstock purification methods, and the strong desire for a much cleaner membrane product to provide a more useful analytical tool, provided those of skill in the art with a great motivation to find and implement an improved membrane production process. If the present invention was nothing more than an obvious rearrangement of process steps,

these cost savings and improved product would have appeared in the market long ago.

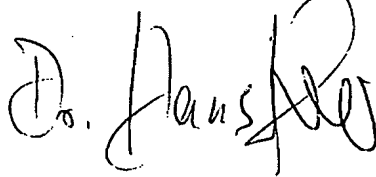
12. In contrast to the prior art, the present invention results in a lower cost, highly clean membrane with properties that one of skill in the art would recognize could not have been obtained by merely rearranging the Beer and/or Johnson steps, *i.e.*, a membrane with a highly uniform test fluid migration (phenol red solution) of 90 seconds/40 mm, with a precise and intensive colored dividing line, due in large part to the lack of membrane damage from dry-membrane brushing and the lack of contaminants which still exist even after a Beer feedstock purification process.

I declare that the preceding statements which are made from my own knowledge are true and that the preceding statements which are made on information and belief are believed to be true.

I am aware that willful false statements and the like are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and may jeopardize the validity of the application or any patent issuing thereon.

February 02, 2006
DATE

Dr. Hans Beer
SIGNATURE

A handwritten signature in black ink, appearing to read "Dr. Hans Beer", written over the printed name and signature line.